

REMARKS

I. Introduction

Upon entry of the present amendment, claims 1-8, 10, 13-18 and 25-38 will be pending in this application. Claims 17 and 27 have been amended to clarify the features of the invention. No new matter has been added.

Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

II. Rejections based on 35 U.S.C. § 103

The Examiner has rejected claims 1-8, 10, 13-18 and 25-38 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,120,546 to Dye et al. in view of U.S. Patent No. 6,152,927 to Farris et al. or U.S. Patent No. 6,228,121 to Khalili. Applicants respectfully traverse these rejections and request reconsideration and withdrawal thereof.

The claims of the application are directed to an insertion member, which can be a screw, peg, opening cover or other device, that includes a rounded nonfrustoconical contact surface adapted to contact the frustoconical taper section of an opening in a prosthesis. These differently-shaped surfaces contact each other when the insertion member is inserted into the opening. The insertion member is adapted to fit the opening of the prosthesis in a substantially fluid-tight relationship, at a plurality of angular orientations between the insertion member and the opening, so that the head of the insertion member does not protrude beyond the first surface.

To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. *See M.P.E.P. § 2142.*

There is no suggestion or motivation to modify the references or to combine reference teachings. *Farris et al.* teaches that in a preferred embodiment, the screw holes include a spherical portion to receive a complimentary formed spherical head of a bone screw. Thus, *Farris et al.* describes contact between two similarly-shaped surfaces. Applicants' claims require contact between two differently-shaped surfaces, the frustoconical taper section of the opening and the rounded, nonfrustoconical contact surface of the insertion member. Thus, one with skill in the art would not be motivated to modify *Farris et al.* in an attempt to achieve the claimed invention.

Furthermore, the prior art references do not teach or suggest all the claim limitations when combined. *Dye et al.* does not disclose contact between two differently-shaped surfaces or that contact between a screw and screw hole 36 provides a fluid-tight seal. On the contrary, *Dye et al.* teaches that the screw hole 36 is used with a bone screw in which the portion of the head adjacent the shank is “convexly spherically shaped with substantially the same radius of curvature as the spherical second portion 40 of screw hole 36.” Col. 7, lines 18-23 (emphasis added). Thus, *Dye et al.* teaches corresponding or congruently shaped surfaces on the screw hole and the screw. Furthermore, it is not inherent that that the “congruent” contact of these surfaces provides a fluid tight seal. The fact that a certain result or characteristic may occur or be present in a reference is not sufficient to establish the

inherency of that result or characteristic. M.P.E.P. § 2112. Applicants respectfully submit that *Dye et al.* does not disclose, either explicitly or inherently, a fluid tight seal between the screw hole and the screw. Should the Examiner maintain this rejection, Applicants respectfully request that the Examiner provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied reference as required by M.P.E.P. § 2112.

Khalili does not disclose an insertion member having a head which includes a rounded nonfrustoconical contact surface adapted to contact the frustoconical taper section of an opening in a prosthesis and adapted to be inserted into the opening such that the contact surface contacts the extended frustoconical taper section. The fixation screw 108 does not mate with aperture 114 and in fact does not contact aperture 114 at all. The fixation screw 108 of *Khalili* mates with the sleeve component 110, which in turn mates with the aperture 114. *Khalili* discloses that a separate sleeve component 110 and fixation screw 108 are necessary to allow the screw head to move longitudinally such that the screw is prevented from contacting and damaging an inner cup component. Col. 2, lines 44-48. The Examiner's rationale that a sleeve component 110 and fixation screw 108 together are an insertion member impermissibly changes the principle of operation of *Khalili*.

In summary, nothing in the references teaches or suggests a rounded, nonfrustoconical contact surface on an insertion member head that contacts a frustoconical surface of the opening so that the insertion member fits in the opening in a substantially fluid tight relationship at a plurality of angular orientations between the opening and the insertion member, whereby the head does not protrude beyond the first or inner surface of the

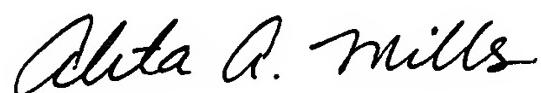
prosthesis or implant, as required in all claims. Applicants respectfully submit that the claims are not rendered obvious by the combination of *Dye et al.*, *Farris et al.* and *Khalili*.

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6409 is respectfully solicited.

Respectfully submitted,



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